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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,621	10/19/2004	Petra Cirpus	12810-00043-US	6556
23416 7590 01/29/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER MCELWAIN, ELIZABETH F	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/511,621

**Applicant(s)**

CIRPUS ET AL.

**Examiner**

Elizabeth F. McElwain

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of R1 as general formula II; R2 as unsaturated C2-C4-alkylcarbonyl; and R3 as unsaturated C2-C4-alkylcarbonyl in the reply filed on November 2, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Objections***

The claims are objected to for the inclusion on non-elected subjected matter.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and claims 2-20 dependent thereon, are indefinite in that, as written, it is unclear whether the recitation of "or a radical of general Formula II" is intended as an alternative to Formula I or as a choice for R1.

Claims 18 and 19 are indefinite in the recitation of “wherein two or more of the first, second and third sequences are selected from said group” of claim 12. It is unclear what “said group” is referring to. If the claim is intended to read on sequences other than those recited in claim 12, then claims 18 and 19 fail to further limit claim 12. Clarification and correction is requested.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of producing in a tobacco plant transformed with the delta-6 elongase of SEQ ID NO: 3, the delta-6 desaturase of SEQ ID NO: 13 and the delta-5 desaturase of SEQ ID NO: 20 the compound represented by 20:3-9765 and 20:4-9938 in Figure 2, does not reasonably provide enablement for the claimed process of producing any and all of the compounds recited in claim 1 having any of C2 to C4 alkylcarbonyl groups as R2 and R3 and by transformation of any plant species with any set of three nucleic acids that may have as little as 50% identity with any of the recited SEQ ID numbers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

6. The claims are drawn to a process of producing any and all of the compounds recited in claim 1 having any of C2 to C4 alkylcarbonyl groups as R2 and R3 and produced in any plant

species. However, the specification only demonstrates a tobacco plant transformed with the delta-6 elongase of SEQ ID NO: 3, the delta-6 desaturase of SEQ ID NO: 13 and the delta-5 desaturase of SEQ ID NO: 20 for the production in the tobacco seeds of the compounds represented by 20:3-9765 and 20:4-9938 in Figure 2. The specification does not provide examples of any other compounds produced in a transgenic plant, and the specification does not provide examples of fatty acid profiles from other plant species or from any plants transformed with other nucleic acid sequences. In addition, the specification does not provide guidance with regard to the identification of any of the compounds recited in claim 1 or with regard to the fatty acid profiles of other plant species.

Furthermore, with regard to claim 12, part c), sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page

132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode a particular activity, one cannot conclude that these other sequences also encode enzymes having the same functional activity.

In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding fatty acid biosynthetic enzymes, and the modification of plant lipid composition by transforming a plant with said gene are highly unpredictable.

Thus, given the unpredictability of producing particular fatty acids in a plant seed of any species by introducing fatty acid biosynthetic genes, and the unpredictability of identifying sequences that exhibit the desired functional activities and modifying the lipid composition of a

plant with said sequences; the lack of guidance in the specification for identifying and characterizing other sequences that exhibit the claimed functional activities and the lack of guidance regarding the production and identification of the compounds recited in claim 1, including choice of nucleic acid sequence and choice of plant species, for example; and given the lack of working examples of any other compounds produced in any other species of plant seed and using any other nucleic acid sequences, and the lack of working examples of similar sequences that encode proteins having the same activity; and given the breadth of the claims which encompass producing a multitude of fatty acids with numerous modifications at any of R1, R2 and R3 and encompassing any of C2 to C24 alkylcarbonyls and producing said compounds and combinations of said compounds in any plant species and using any of the claimed nucleic acid sequences having as little as 50% identity to the sequences listed; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

No claims are allowed.

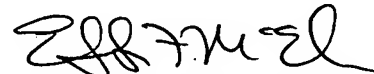
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Elizabeth F. McElwain  
Primary Examiner  
Art Unit 1638

EFM